

## InDex Pharmaceuticals Holding AB (publ)

Interim report January-March 2017

The CONDUCT study starts

#### PERIOD JANUARY-MARCH 2017

- Revenues amounted to SEK 0.0 (0.0) million
- Operating result amounted to SEK –22.1 (–6.9) million
- Result after tax amounted to SEK –22.0 (–7.1) million, corresponding to SEK –0.35 per share (–0.23) before and after dilution
- Cash flow from operating activities amounted to SEK –19.1 (12.5) million
- Cash and cash equivalents at the end of the period amounted to SEK 174.1 (19.5) million
- Number of employees at the end of the period was 7 (8)
- Number of shares at the end of the period was 62 528 433

All comparative amounts in brackets refer to the outcome of InDex's overall activities during the corresponding period 2016.

#### SIGNIFICANT EVENTS DURING JANUARY-MARCH 2017

- The company has entered an agreement for services with a global contract research organization (CRO) for the implementation of the CONDUCT study
- InDex participated with two poster presentations at the annual congress of the European Crohn's and Colitis Organisation (ECCO)
- Johan Giléus was appointed as new Chief Financial Officer (CFO) from May 1, 2017
- A new patent covering 19 substances from the company's DIMS platform was granted in the US
- InDex hosted a well attended investigators' meeting for the CONDUCT study

#### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

 InDex participated with two poster presentations at the Digestive Disease Week (DDW)

"The work on the CONDUCT study is progressing according to plan and we will start treating patients during the second quarter of this year. Several clinics are now activated and ready to enroll patients."

Peter Zerhouni, CEO

#### **INDEX IN BRIEF**

InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company's foremost asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe active ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in treatment of various immunological diseases. InDex is based in Stockholm, Sweden. The company's shares are traded on Nasdaq First North Stockholm. Redeye AB is the company's Certified Adviser.



### **CEO** statement

InDex's focus remains on the implementation of the phase IIb study CONDUCT with our lead drug candidate cobitolimod. The work is progressing according to plan and we will start treating patients during the second quarter of this year. Several clinics are now activated and ready to enroll patients.

The dose optimisation study will include 215 patients with moderate to severe active ulcerative colitis. The objective is that the last patient will enter the study in the fall of 2018 and that we thereby may have the main results from the study during the fourth quarter of 2018. Please read more about living with ulcerative colitis and the CONDUCT study in InDex's recently published annual report for 2016.

To conduct such a large clinical trial across 12 countries and 90 clinics is a complex project that requires careful preparation and involves hundreds of people with different competences. We have therefore chosen to collaborate with a leading global contract research organization (CRO) for the implementation of the study. They have people on the ground in all countries and in addition considerable experience from managing multinational clinical studies in inflammatory bowel disease. I can also note that the significant experience and expertise that we have internally at InDex regarding conducting clinical studies have contributed to the completion of the study preparations.

The study has been approved by the Medical Products Agencies in several countries and the application process is ongoing in the rest of the countries. In addition to the approval by the Medical Products Agency, approval by an ethics committee is required in each country. In most countries, there is a central committee, but some countries require local approval for each clinic. We will have submitted applications to more than 40 ethics committees in 12 different languages. Before a clinic can be activated, we also need to have an agreement in place with the hospital, which amounts to quite an extensive administrative task given the number of clinics.

The logistics of the study is another area that is now in place. Study drug and sampling kits are sent to the clinics upon request and patient samples are sent from the clinics to a central laboratory in the Netherlands for analysis. Everything should arrive within one day and be shipped at a certain temperature, also from the most distant clinics in, for example, Russia and Ukraine.

However, the most important work is that performed by the clinics, and we attach great importance to keeping them engaged in the study and motivated to recruit patients. In March 2017, we therefore gathered the study teams from the clinics for an investigators' meeting in Stockholm, which was very successful. It was great to see the interest and commitment from the meeting participants.

I look very much forward to report on InDex's significant progress during the past year at the BIO Convention in San Diego, 19-22 June 2017. BIO is the pharmaceutical industry's largest networking event with some 16,000 representatives from drug development companies and larger pharmaceutical companies looking for innovative products for their portfolios.

### **Business overview**

InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company's foremost asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe ulcerative colitis - a debilitating, chronic inflammation of the large intestine. In addition, InDex has a broad portfolio of other DNA based ImmunoModulatory Sequences (DIMS) in discovery stage, with the potential to be used in the treatment of various immunological diseases.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, abdominal pain, fever, weight loss and anemia. Despite the currently available drugs on the market, many patients with ulcerative colitis still suffer from severe symptoms. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon.

InDex's clinical studies indicate that cobitolimod has a higher efficacy and a more favourable safety profile than what has been reported for the currently approved biological drugs in corresponding patient populations. Sales of biologics for treatment of ulcerative colitis amount to more than USD 4 billion a year.

Cobitolimod has a new type of mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis. Cobitolimod has achieved clinical proof-of-concept in moderate to severe active ulcerative colitis, with a very favorable safety profile. Data from four placebo-controlled clinical trials show that cobitolimod has statistically significant effects on those endpoints that are most relevant in this disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing, respectively.

Based on the encouraging results from earlier studies InDex is now performing a phase IIb study to evaluate other doses and dose frequencies than investigated in previous studies with cobitolimod. The goal of the study is to optimise the treatment and achieve substantially higher efficacy, while maintaining the compound's excellent safety profile. Cobitolimod is also known as Kappaproct<sup>®</sup> and DIMS0150.

#### SIGNIFICANT EVENTS DURING THE REPORTING PERIOD

- The company entered an agreement for services with a contract research organization (CRO) on January 31, 2017 for the implementation of the CONDUCT study. The objective is to have top line results from the study in the fourth quarter of 2018. The study will be conducted at approximately 90 sites in 12 different countries.
- InDex participated with two poster presentations at the 12th congress of the European Crohn's and Colitis Organisation (ECCO), which was held in Barcelona, Spain on February 15-18, 2017. The ECCO congress is the largest congress in the world with a specific focus on inflammatory bowel disease (IBD).
- InDex announced on March 8, 2017 that the company has appointed Johan Giléus as new Chief Financial Officer (CFO) from May 1, 2017.
- InDex announced on March 14, 2017 that a patent covering 19 compounds from the company's DIMS platform has been granted by the United States Patent and Trademark Office (USPTO).
- InDex hosted a well attended investigators' meeting for the CONDUCT study on March 20-21, 2017. The meeting gathered physicians, study nurses and study coordinators from 65 clinics in 11 countries together with personnel from InDex and the contract research organization (CRO). A total of almost 170 attendees participated in the meeting which was held in the Nobel prize lecture hall Aula Medica at Karolinska Institutet in Stockholm.

#### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

 InDex participated with two poster presentations at the Digestive Disease Week (DDW), which was held in Chicago, US on May 6-9, 2017. DDW is the largest congress in the world within gastroenterology.

#### CORPORATE STRUCTURE

InDex Pharmaceuticals Holding AB was incepted on December 14, 2015 and was registered with the Swedish Companies Registration Office on June 27, 2016. At an Extra General Meeting held on August 25, 2016 it was resolved, and on September 7, 2016 an issue for non-cash consideration was registered at the Swedish Companies Registration Office, whereby the shareholders of InDex Pharmaceuticals AB transferred 99.76 percent (in March 2017 99.97 percent had been

FINANCIAL SUMMARY				
MSEK	Jan-Mar 2017	Jan-Mar 2016	Full year 2016	Full year 2015
Revenues	0.0	0.0	0.4	0.4
Operating result	-22.1	-6.9	-39.5	-29.5
Result after tax	-22.0	-7.1	-41.3	-29.9
Result per share before and after dilution, SEK	-0.35	-0.23	-1.08	-0.99
Cash flow from operating activities	-19.1	12.5	-31.9	-37.0
Cash and cash equivalents at the end of the period	174.1	19.5	193.2	7.0

Note: Result per share - Net result divided by average number of shares

transferred) of the shares in the company in exchange for new shares in the new parent company, InDex Pharmaceuticals Holding AB. The intention is that also the remaining shares in InDex Pharmaceuticals AB will be exchanged for shares in the parent company.

With the support of valuations provided by two independent external parties, the Board attributed the shares in InDex Pharmaceuticals AB a total value of SEK 247.0 million, out of which the shares held by the parent company were reported in the balance sheet at the same value, as the remaining shares will be transferred alternatively compulsory acquired. A debt of SEK 0.1 million to the minority shareholders (the few shareholders that have not signed the share exchange agreement, representing 0.03 percent of total shares) have therefore been reported as of March 31, 2017. After registration of the various decisions taken as part of the formation of the new group, the share capital in InDex Pharmaceuticals Holding AB amounted to SEK 601,344.68, divided into 30,067,234 shares (after simultaneous withdrawal and consolidation of shares).

At a board meeting of InDex Pharmaceuticals Holding AB on September 13, 2016 it was resolved to issue a maximum of 29,761,905 new shares at a subscription price of 8.40 SEK per share in order to raise working capital and to broaden the shareholder base prior to a listing of the shares, as well as a directed issue of a maximum of 2,634,279 new shares at a subscription price equivalent to the par value per share. The latter issue was directed to the existing owner of preference shares (NeoMed Management/N5) in order to allow only one class of shares going forward. The new share issues were fully subscribed, of which a small lot of 29,540 shares was registered after the end of the year. After the registration of these remaining shares there will in InDex Pharmaceuticals Holding AB be a registered capital of SEK 1,250,569 divided into a total of 62,528,433 shares.

As InDex Pharmaceuticals Holding AB was registered at the Swedish Companies Registration Office on June 27, 2016, there are no comparative periods in the financial statements of the legal parent company.

The Board has concluded that the restructuring described above has not in itself changed the business or the shareholder structure, why the consolidated financial statements have been prepared in accordance with the guidelines for acquisition under common control. In short this means that the consolidated financial statements are prepared as if InDex Pharmaceuticals AB is the acquiring company in the consolidated financial statements and, therefore, the assets and liabilities are reported at historical values. This further means that the comparative periods for InDex can be presented in the financial report for InDex where InDex Pharmaceuticals AB was the legal parent.

#### FINANCIAL SUMMARY FOR THE REPORTING PERIOD

Operating costs amounted to SEK 22.1 million, which is an increase with SEK 15.1 million compared to the corresponding period the previous year. The large increase is mainly attributable to the ongoing phase IIb study and the cost for a large batch of cobitolimod substance.

Costs for the personnel decreased with 4 percent mainly attributable to the lower number of employees 2017 (one FTE less) compared to the corresponding period last year.

Cash and cash equivalents as of March 31, 2017 amounted to SEK 174.1 million, which is SEK 19.1 million lower than December 31, 2016.

#### FINANCIAL SUMMARY AFTER THE REPORTING PERIOD

No significant events have occurred after the end of the reporting period.

#### EMPLOYEES

The number of employees at the end of the period was 7 (8).

#### THE SHARE

The share is listed on Nasdaq First North Stockholm since October 11, 2016.

#### LARGEST SHAREHOLDERS PER MARCH 31, 2017

	Number of shares	Percentage of capital and votes, %
SEB Venture Capital	14,657,241	23.4
Stiftelsen Industrifonden	12,900,272	20.6
NeoMed/N5	6,907,913	11.1
Staffan Rasjö	3,124,718	5.0
SEB Stiftelsen	1,785,714	2.9
Avanza Pension	1,620,188	2.6
Danske Bank International	1,083,512	1.7
Nordnet Pensionsförsäkring	1,026,241	1.6
Rune Petterson	980,081	1.6
Ponderus Securities	898,117	1.4
Others	17,544,436	28.1
Total	62,528,433	100.0

#### **INCENTIVE PROGRAMMES**

InDex Pharmaceuticals Holding AB had three incentive programs during the period. The first two could be exercised between March 1 and April 30, 2017 and had an exercise price of SEK 14 per share. The two programs comprised 3,216,477 warrants in total. On April 30, 2017 the two incentive programs matured and no new shares were issued.

At the Extraordinary General Meeting held on September 12, 2016 it was resolved to issue an additional 3,250,000 warrants to transfer to employees and other key persons within InDex. The warrants have an exercise price of SEK 19 per share and can be exercised in September 2019. Within this program, 3,062,500 warrants have been subscribed for during October, 2016 and have been acquired at fair value by employees and other key persons in InDex.

#### TRANSACTIONS WITH RELATED PARTIES

InDex Pharmaceuticals Holding AB invoices its subsidiaries for group wide services.

#### PRINCIPLES FOR PREPARATION OF THE INTERIM REPORT General information

This interim report has been prepared in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 (K3). See also under "Corporate Structure" for additional information about the completed legal restructuring.

The accounting policies adopted in this interim report are consistent with those of the 2016 annual report and should be read in conjunction with that annual report.

#### **REVIEW BY THE AUDITOR**

This report has not been reviewed by the company's auditor.

#### PROSPECTS, RISKS AND UNCERTAINTIES

There is no guarantee that InDex's research and development will result in commercial success. There is no guarantee that InDex will develop products that can be patented, that granted patents can be retained, that future inventions will lead to patents, or that granted patents will provide sufficient protection for InDex's products.

There is no guarantee that InDex obtains necessary approvals to conduct the clinical trials that InDex would like to implement, or that the clinical trials conducted by InDex, independently or in collaboration with partners, will demonstrate sufficient safety and efficacy to obtain necessary regulatory approvals or that the trials will lead to drugs that will be sold on the market. It cannot be excluded that the regulatory approval process will require increased documentation and thereby increased costs and delays in projects or lead to projects being shut down. Increased development costs and longer development time may mean that the risks of a project increases and that the compound's potential to successfully reach the commercial stage decreases or that the time for patent protected sales is reduced. InDex may also in the future need to raise additional capital. Both the size and timing of InDex's potential future capital requirements will depend on a number of factors, including opportunities to enter into collaboration or licensing agreements and the progress made in research and development projects. There is a risk that the required financing for the operations will not be available at the right time and at reasonable cost. For a more detailed description of risk factors, please refer to the annual report for 2016, which is available on the company's web page.

#### FINANCIAL CALENDER

Interim report Q II 2017	August 25, 2017
Interim report Q III 2017	November 17, 2017
Year-end report 2017	February 15, 2018

Stockholm May 30, 2017 Peter Zerhouni, CEO

#### FOR MORE INFORMATION, PLEASE CONTACT:

Peter Zerhouni, CEO Phone: +46 (0) 8 508 847 30 Email: peter.zerhouni@indexpharma.com

InDex Pharmaceuticals Holding AB (publ) Tomtebodavägen 23a, 171 77 Stockholm, Sweden www.indexpharma.com

The information in this interim report is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication at 8:00 CET on May 30, 2017.

This is an English translation of the Swedish interim report. In case of discrepancies between the English translation and the Swedish report, the Swedish report shall prevail.

## **Consolidated income statement**

	Jan 1-Mar 31,	Jan 1-Mar 31,	Jan 1-Dec 31,
SEK 000's	2017	2016	2016
Revenues			
Net sales	35	50	176
Other income	-	-	209
Total revenues	35	50	385
Operating expenses			
Raw material and consumables	-8,204	-297	-6,301
Other external expenses	-11,656	-4,310	-24,313
Personnel costs	-2,264	-2,364	-9,253
Depreciations	-3	-14	-67
Total expenses	-22,127	-6,985	-39,934
Operating loss	-22,092	-6,935	-39,549
Profit/loss from financial items			
Financial income	109	95	260
Financial expenses	-60	-240	-1,986
Total	49	-145	-1,726
Earnings before tax	-22,043	-7,080	-41,275
Taxes for the period	-	-	-
Net profit/loss for the period	-22,043	-7,080	-41,275
Loss per share, before and after dilution, SEK	-0.35	-0.23	-1.08
Average number of shares	62,524,166	30,140,793	38,110,575
Number of shares at the end of the period	62,528,433	30,140,793	62,498,893

## **Consolidated balance sheet**

SEK 000's	Mar 31, 2017	Mar 31, 2016	Dec 31, 2016
ASSETS			
Fixed assets			
Intangible fixed assets			
Patents, license and trademarks	-	-	-
Tangible fixed assets			
Equipment, tools and installations	40	43	43
	+0		64
Total fixed assets	40	43	43
Current assets			
Current receivables			
Accounts receivable	25	44	285
Other current receivables	1,052	719	358
Prepaid expenses and accrued income	624	767	568
Total current receivables	1,701	1,530	1,211
Cash and cash equivalents	174,133	19,509	193,232
Total current assets	175,834	21,039	194,443
TOTAL ASSETS	175,874	21,082	194,486
EQUITY AND LIABILITIES Restricted equity			
Share capital	1,251	6,028	1,250
Ongoing share issue		0,020	1,230
Total restricted equity	1,251	6,028	1,251
Non-restricted equity			
Share premium	216,934	-	216,934
Retained earnings	-40,714	-5,478	561
Loss for the period	-22,043	-7,080	-41,275
Total non-restricted equity	154,177	-12,558	176,220
Total equity	155,428	-6,530	177,471
Current liabilities			
Accounts payables	8,015	969	4,822
Other liabilities	5,820	22,881	5,608
Accrued expenses and deferred income	6,611	3,762	6,585
Total current liabilities	20,446	27,612	17,015
TOTAL EQUITY AND LIABILITIES	175,874	21,082	194,486
	175,074	21,002	154,400

# **Consolidated statement of changes in equity**

	Share	Share	Retained	
SEK 000's	capital	premium	earnings	Net result
Opening balance, January 1, 2016	6,028	-	24,404	-29,882
Disposition of last year's result	-	-	-29,882	29,882
Net result	-	-		-7,080
Closing balance, March 31, 2016	6,028	_	-5,478	-7,080
Opening balance, January 1, 2016	6,028	_	24,404	-29,882
Disposition of last year's result	-	-	-29,882	29,882
Effects from transaction under common control	-5,427	-	5,427	-
Issues of shares	650	249,403	-	-
Issue costs	-	-32,469	-	-
Issue of warrants	-	-	612	-
Net result	-	-	-	-41,275
Closing balance, December 31, 2016	1,251	216,934	561	-41,275
Opening balance, January 1, 2017	1,251	216,934	561	-41,275
Disposition of last year's result	-	-	-41,275	41,275
Net result	-	-	-	-22,043
Closing balance, March 31, 2017	1,251	216,934	-40,714	-22,043

## **Consolidated cash flow**

SEK 000's	Jan 1-Mar 31, 2017	Jan 1-Mar 31, 2016	Jan 1-Dec 31, 2016
Operating activities			
Earnings before tax	-22,043	-7,080	-41,275
Adjustments for non-cash items			
Depreciations	3	14	67
Income tax paid	-	-	-
Cash flow from operating activities before changes in working capital	-22,040	-7,066	-41,208
Changes in working capital			
Changes in current receivables	-490	-192	127
Changes in current liabilities	3,431	19,807	9,211
Cash flow from changes in working capital	2,941	19,615	9,338
Cash flow from operating activities	-19,099	12,549	-31,870
Investing activities			
Acquisition of tangible assets	-	-	-53
Cash flow from investing activities	-	-	-53
Financing activities			
Issues of shares	-	-	217,583
Issues of warrants	-	-	612
Cash flow from financing activities	-	-	218,195
Cash flow for the period	-19,099	12,549	186,272
Cash and cash equivalents at the beginning of the period	193,232	6,960	6,960
Cash and cash equivalents at the end of the period	174,133	19,509	193,232

### Income statement parent company

	Jan 1-Mar 31,	Jun 27-Dec 31,
SEK 000's	2017	2016
Revenues		
Net sales	1,626	1,156
Total income	1,626	1,156
Operating expenses		
Other external expenses	-1,784	-1,427
Personnel costs	-1,072	-351
Total expenses	-2,856	-1,778
Operating loss	-1,230	-622
Net financial items		
Write-down of financial assets	-60,000	-47,000
Financial costs	-1	-
Total	-60,001	-47,000
Earnings before tax	-61,231	-47,622
Taxes for the period	-	-
Net profit/loss for the period	-61,231	-47,622

## **Balance sheet parent company**

SEK 000's	Mar 31, 2017	Dec 31, 2016
ASSETS		
Fixed assets		
Financial assets		
Shares in subsidiary	247,030	247,030
Total fixed assets	247,030	247,030
Current assets		
Current receivables		
Other receivables	-	248
Prepaid expenses and accrued income	349	325
Total current receivables	349	573
Cash and cash equivalents	159,613	188,386
Total current assets	159,962	188,959
TOTAL ASSETS	406,992	435,989
EQUITY AND LIABILITIES		
Restricted equity		
Share capital	1,251	1,250
Ongoing share issue	-	1
Total restricted equity	1,251	1,251
Non-restricted equity		
Share premium	463,294	463,294
Retained earnings	-46,972	650
Net result	-61,231	-47,622
Total non-restricted equity	355,091	416,322
Total equity	356,342	417,573
Current liabilities		
Accounts payable	847	923
Intercompany liabilities	48,300	16,973
Other liabilities	273	258
Accrued expenses and deferred income	1,230	262
Total current liabilities	50,650	18,416
TOTAL EQUITY AND LIABILITIES	406,992	435,989

# Statement of change in equity parent company

Closing balance, March 31, 2017	1,251	463,294	-46,972	-61,231
Net result	-	_		-61,231
Disposition of last year's result			-47,622	47,622
Opening balance, January 1, 2017	1,251	463,294	650	-47,622
Closing balance, December 31, 2016	1,251	463,294	650	-47,622
Net result	-	-	-	-47,622
Issue of warranties	-	-	650	-
Issue costs	-	-32,469	-	-
Issue of shares	650	249,403	-	-
Share issue in-kind/reduction of number of shares	101	246,360	-	-
Inception of the company, June 27, 2016	500	-	-	-
SEK 000's	Share capital	Share premium	Retained earnings	Net result

## Development of parent company's share capital

SEK		Change in	Total share	Number of	Total number	Paid in
Date	Transaction	share capital	capital	new shares	of shares	amount
Jun 27, 2016	Inception of the company	500,000	500,000	500,000	500,000	500,000
Sep 7, 2016	Split of shares	-	500,000	45,500,000	50,000,000	-
Sep 7, 2016	Share issue in-kind	601,345	1,101,345	60,134,466	110,134,466	-
Sep 7, 2016	Reduction of number of shares	-500,000	601,345	-50,000,000	60,134,466	-
Sep 7, 2016	Share issue	-	601,345	2	60,134,468	-
Sep 8, 2016	Reversed split of shares	-	601,345	-30,067,234	30,067,234	-
Oct 10, 2016	Share issue for pref. shares	52,685	654,030	2,634,279	32,701,513	52,685
Oct 10, 2016	Share issue	560,479	1,214,509	28,023,969	60,725,482	235,401,340
Oct 12, 2016	Share issue	14,305	1,228,814	715,250	61,440,732	6,008,100
Oct 25, 2016	Share issue	17,969	1,246,783	898,421	62,339,153	7,546,736
Nov 14, 2016	Share issue	1,895	1,248,678	94,725	62,433,878	795,690
Dec 29, 2016	Share issue in-kind	1,300	1,249,978	65,015	62,498,893	-
Jan 13, 2017	Share issue	591	1,250,569	29,540	62,528,433	248,136